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EXAMINER	
LUBIN, VALERIE	
ART UNIT	PAPER NUMBER
3626	
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04/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/748,081	PETERSON ET AL.	
	Examiner	Art Unit	
	VALERIE LUBIN	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48 and 50-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-48, 50-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgements

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Claims 1-48, 50-60 are pending

For reference purposes, the document paper number is 20080409

Response to Arguments/Amendments

2. Applicant's arguments filed 02/20/09 have been fully considered but they are not persuasive.

3. For claims 1, 27 and their dependents, Applicant argues that Klein does not disclose a system wherein a subsequent start date is determined by an alteration in a drug's future

usage. Examiner respectfully disagrees, as Applicant admits in his arguments that "Klein discloses a system that can support complex dosage schedules where administration levels, routines and instruction may change each specific time the drug is administered." Hence, Klein's disclosed invention also reads on determinations based on alterations in drug usage.

For claims 20, 54 and their dependents, Applicant argues that neither Klein nor Rotten disclose determining a risk period from digital patient information and at least a start time. Examiner respectfully disagrees. Klein does disclose a start time and patient digital information (¶ 16-18). Klein does not recite determining a risk period, but Rotten does (Abstract). The variables on which such risk is determined are a substitution of known variables for other known variables taught by Klein that produces predictable results (Ex parte Smith, 83 USPQ2d 1509 (Bd. Pat. App. & Int. 2007)).

4. The rejection of claims 1-26 and 31 under 35 USC § 101 is withdrawn in light of Applicant's amendment.

5. The rejection of claims 6-13, and 27-30, 32-60 under 35 USC § 112, 2nd paragraph is withdrawn in light of Applicant's amendment. The rejection of claim 31 however is maintained.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 31 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 31 is indefinite because it recites a computer-readable medium, but depends from claim 26 which is method claim. Furthermore, claim 26 does not recite a calendar. For examining purposes, the claim shall be considered a dependent of claim 27 or 30.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1- 8, 18, 19, are 27-35, 46, 50, 52 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein U.S. Pre-Grant Pub No. 2002/0026330.

11. With respect to claim 1, Klein discloses a method performed by a computing device comprising the steps of selecting a least one drug associated with a predetermined digital

patient information (¶ 16, 18); identifying a first start time for administering at least one drug dosage (¶ 17); determining an initial future drug usage from the digital patient information and the first start time (¶32); and identifying a least one subsequent start time and determining a subsequent future drug usage period (¶ 32).

Klein does not specifically recite identifying a least one subsequent start time based on an alteration in the subject's future drug usage; however he does indicate changing dosages and schedules (¶ 10). Therefore, one of ordinary skill in the art would know to change or maintain the schedule for administering a drug based on some change in the drug dosage or the patient's condition in order to better treat such patient.

Furthermore, the last two limitations of claim 1 are repetitions of the second and third limitations, and it has been held that the "mere duplication of parts has no patentable significance unless a new and unexpected result is produced" (In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960)).

Claims 18 and 19 are rejected under the analysis of claim 1.

Claims 27, 52 and 53 are rejected under the analysis of claim 1, as Klein discloses a computer program or software (¶ 28, 31), a memory (¶ 31) and a processor (¶ 28) for performing the steps found in claim 1.

12. Claim 2 is rejected, as Klein recites visually presenting on a computer display the initial future drug usage period (¶ 35, 36).

Claim 3 is rejected under the analysis of claim 2, as it is a mere duplication of claim 2.

Claims 28 and 29 are also rejected under the analysis of claim 2.

13. For claim 4, Klein does not specifically recite the visual presentation of the periods being in the form of a calendar; however, he recites monitoring drug usage using a calendar (¶ 32) and displaying a drug usage period on a computer (¶ 35, 36). A predictable result of Klein would therefore be to display the calendar used to monitor the drug usage period on the computer display (KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007)).

Claim 5 is rejected under the analysis of claim 4, as the type of calendar displayed is non-functional descriptive material that does not further limit the step of displaying a drug usage period using a calendar (In re Gulack, 217 USPQ 401 (Fed. Cir. 1983), In re Ngai, 70 USPQ2d (Fed. Cir. 2004), In re Lowry, 32 USPQ2d 1031 (Fed. Cir. 1994); MPEP 2106.01 II).

Claims 30 and 31 are rejected under the analysis of claims 4.

14. Claim 6 is rejected, as Klein discloses storing drug data comprising at least drug usage in a memory (¶ 31, 39).

Claim 7 is rejected under the analysis of claim 6.

Claims 32-34 are rejected under the analysis of claim 6.

15. Claim 8 is also rejected, as Klein recites drug data being accessible by at least one party (¶ 39).

Claim 35 is rejected under the analysis of claim 8.

16. Claim 46 is rejected because Klein recites a personal digital assistant (¶ 28).

17. For claim 50, Examiner takes Official notice that storing software on a computer executable medium such as a compact disk or a floppy was old and well known in the art at the time the invention was made. Therefore, one of ordinary skill in the art would know to combine the teachings of Klein with the prior art in order to be able to run the program on different microprocessors.

18. Claims 9-17, 36-45, 47, 48 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein U.S. Pre-Grant Pub No. 2002/0026330 in view of Stasny Pre-Grant Pub No. 2003/0074234.

19. With respect to claim 9, Klein recites drug data being accessible by at least one party (¶ 39). Klein does not recite the at least one party offering at least one recommendation based on the drug data, but Stasny does (¶ 4, 5, 50). It would therefore have been obvious to combine the teachings of Klein with those of Stasny in order to allow customers to have access to a variety of products and make better drug selection decisions.

Claim 39 is rejected under the analysis of claim 9.

20. Claim 10 is rejected, as Stasny discloses a pharmaceutical company recommending purchases of pharmaceutical products (¶ 50).

Claim 40 is rejected under the analysis of claim 10.

21. Claim 11 is rendered obvious, as Stasny recites a customer accessing drug data that is tailored for the customer based on the customer's profile (¶ 50).

Claim 12 is rejected under the analysis of claim 11, as the type of characteristics by which the drug data is grouped is non-functional descriptive material that does not further limit the method claim of grouping the drug data (In re Gulack, 217 USPQ 401 (Fed. Cir. 1983), In re Ngai, 70 USPQ2d (Fed. Cir. 2004), In re Lowry, 32 USPQ2d 1031 (Fed. Cir. 1994); MPEP 2106.01 II).

Claims 36 and 37 are also rejected under the analysis of claim 11.

22. Claim 13 is rejected, as Stasny recites a pharmaceutical company, a health care professional, an insurance company, and a party authorized to access the subject's drug data (Abstract).

Claim 38 is rejected under the analysis of claim 13.

23. Claim 14 is rejected, as Stasny recites educational information about a drug (¶ 45, 50, 53, 60).

Claims 41 and 42 are rejected under the analysis of claim 14.

24. Claim 15 is also rejected, as Klein and Stasny disclose instructions to aid in administering the drug (Klein: ¶ 38; Stasny: ¶ 52, 60).

Claim 43 is rejected under the analysis of claim 15.

25. With respect to claim 16, Klein does not specifically disclose identifying an issue by visually presenting instructions; however, Stasny discloses a customer requesting information (¶ 78, 81) and displaying information about a prescription including directions (¶ 83). Claim 16 is thus rendered obvious over Klein and Stasny, because a predictable result of Stasny

would be to request more information on an issue identified in the displayed information (KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007)).

Claim 44 is rejected under the analysis of claim 16.

26. With regards to claim 17, it is rejected under the analysis of claim 16 because the type of drug to which the method is applied to and the type of issue to be addressed are non-functional descriptive material that do not further limit the method steps found in parent claim 16 (In re Gulack, 217 USPQ 401 (Fed. Cir. 1983), In re Ngai, 70 USPQ2d (Fed. Cir. 2004), In re Lowry, 32 USPQ2d 1031 (Fed. Cir. 1994); MPEP 2106.01 II).

Claim 45 is rejected under the analysis of claim 17.

27. Claims 47 and 48 are rejected, as Stasny recites multimedia presentations including audio, video presentations and hyperlinks to web pages (¶ 60).

28. Claim 51 is rejected, as Stasny discloses using the internet (¶ 46, 47).

29. Claims 20- 22, and 54-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein U.S. Pre-Grant Pub No. 2002/0026330 in view of Rottem, U.S. Patent No. 6,769,602.

30. With respect to claim 20, Klein discloses a method comprising the steps of selecting a least one drug associated with a predetermined digital patient information (¶ 16, 18); identifying at least one start time for administering at least one drug dosage (¶ 17); and

determining a future drug usage from the digital patient information and the at least one start time (¶32).

Klein does not recite determining a risk period, but Rottem does (Abstract). It would therefore have been obvious to one of ordinary skill in the art to combine the teachings of Klein and Rottem to determine a risk period based on the patient data and the start time of administering a drug as taught by Klein in order to better monitor patient's response to the administered drug and to determine following courses of action.

Claim 54 is rejected under the analysis of claim 20.

31. Claim 21 is rendered obvious, as Klein recites visually displaying a drug usage period on a computer display (¶ 35, 36). A predictable result of Klein would be to display any period affected by drug usage such as a risk period (KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007)).

Claim 55 is rejected under the analysis of claim 21.

32. Claim 22 is rejected, as Klein recites educational information about at drug (¶ 38).

Claim 56 is rejected under the analysis of claim 22.

33. Claims 23-26 and 57-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein U.S. Pre-Grant Pub No. 2002/0026330 in view of Rottem, U.S. Patent No. 6,769,602, further in view of Stasny Pre-Grant Pub No. 2003/0074234.

34. With respect to claim 23, Klein and Rottem do not specifically recite educational information including at least a risk associated with a drug, but Stasny does (¶ 52, 83).

Claim 57 is rejected under the analysis of claim 23.

35. Claim 24 is rejected, as Stasny recites side-effects (¶ 52). Furthermore, the type of risk data included in the educational information in non-functional descriptive material that does not further limit the parent claim 23 (In re Gulack, 217 USPQ 401 (Fed. Cir. 1983), In re Ngai, 70 USPQ2d (Fed. Cir. 2004), In re Lowry, 32 USPQ2d 1031 (Fed. Cir. 1994); MPEP 2106.01 II).

Claim 59 is rejected under the analysis of claim 24.

36. With regards to claim 25, it has been held that a "clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim" ((Texas Instruments Inc. v. International Trade Commission 26, USPQ2d 1010 (Fed. Cir. 1993); Griffin v. Bertina, 62 USPQ2d 1431 (Fed. Cir. 2002); Amazon.com Inc. v. Barnesandnoble.com Inc., 57 USPQ2d 1747 (CAFC 2001)). Claim 25 is therefore rejected under the analysis of claim 23.

Claim 58 is rejected under the analysis of claim 25.

37. With regards to claim 26, it is rejected under the analysis of claim 25 because the type of drug to which the method is applied to and the type of risk identified, are non-functional descriptive material that do not further limit the method steps found in parent claim 20, from

which claims 23 and 25 depend (In re Gulack, 217 USPQ 401 (Fed. Cir. 1983), In re Ngai, 70 USPQ2d (Fed. Cir. 2004), In re Lowry, 32 USPQ2d 1031 (Fed. Cir. 1994); MPEP 2106.01 II).

Claim 60 is rejected under the analysis of claim 26.

Conclusion

38. Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE LUBIN whose telephone number is (571)270-5295. The examiner can normally be reached on Monday-Friday 7:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher L. Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VL

/C. Luke Gilligan/
Supervisory Patent Examiner, Art Unit 3626